13

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,464	04/05/2005	Tara Nylese	10442-004	4794

29391 7590 04/10/2006

BEUSSE BROWNLEE WOLTER MORA & MAIRE, P. A.
390 NORTH ORANGE AVENUE
SUITE 2500
ORLANDO, FL 32801

EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/530,464	NYLESE, TARA	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *2-9 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 10-21* is/are rejected.

7)☒ Claim(s) *15 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1 and 10 – 21 in the reply filed on January 18, 2006 is acknowledged. The traversal is on the ground(s) that the lack of unity is in error because claim 22 is generic to Groups II – IV, and therefore, links these groups together, and further the cited reference of Lu, which teaches a test device that tests for multiple analytes, does not anticipate all of the device claims and therefore, can not be used to break unity between Groups I-IV. This is not found persuasive because the proposed "special" technical feature presented in claim 22 that links the device Groups II-IV is a plurality of regions capable of generating a signal in response to a minimum level of analyte in the sample. This feature is in fact presented by the cited Lu reference (US 6,203,757), wherein the device of Lu comprises a substrate (23), a plurality of membranes (26a-e) in the form of test strips, each containing a test or capture zone, which is responsive to an analyte (target chemical) (see Figures 2 and 3; and columns 6 – 7, in particular). Further, the device can be utilized to test for only one analyte, wherein each test strip comprises a detection of a different concentration of the analyte in order to establish a semi-quantitative analysis (see claims 1 and 2, in particular). Thus, the Applicant's "special" technical feature which links Groups I – IV is known in the art and therefore, lack of unity exists because the inventions do not form a general inventive concept, as they do not share a common special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Specification

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art

known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international

application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

The specification contains the Background of the Invention, part (f), and the Brief Summary of the Invention, part (g), in one complete section. As noted above, these two sections need to be distinct and separate parts from each other.

Appropriate correction is advised.

The disclosure is objected to because of the following informalities:

On page 8, line 4, the first patent number in this line is missing a number.

On page 14, line 10 of the specification, reference is disclosed with regard to Figure 2C, however, this figure is not included within the drawings.

On page 15, line 12, the following phrase is disclosed with regard to Figure 5, "all formed on substrate 72 (not shown)" however, this reference number "72" is presented in Figure 5, so the "(not shown)" is incorrect.

On page 16, lines 31, the test device "100" is mentioned, however, this test device does not exist in any of the figures.

Appropriate correction is required.

Claim Objections

Claims 15 and 16 are objected to because of the following informalities:

Claims 15 and 16 recite the term "the measurably distinguishable sensitivity levels" and should perhaps include the term "multiple" before "measurably distinguishable" in order to remain consistent with the first recitation of this term presented in claim 10.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10 – 13, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "sufficient to induce a response," which is vague and indefinite because it is unclear what type of "response" is created to indicate the "sufficient" level of analyte.

Claim 1 also recites the term "the test unit regions," which lacks antecedent basis.

Claims 10 – 12 and 20 recite the phrase "an opportunity to indicate the presence of analyte in the sample," which is vague and indefinite because it is unclear what

exactly is the "opportunity" given to the first regions in order to indicate the presence of the analyte and how is the presence of the analyte indicated?

Claim 13, which is dependent on claim 10, recites the term "said one measurably distinguishable sensitivity level," which lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 10 – 16 and 19 – 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer et al. (WO 98/39657).

Boehringer et al. teach a lateral flow assay method for monitoring changes in analyte concentration (level) in a sample (source), the method comprising: defining

multiple measurable distinguishable sensitivity level each indicative of a different amount, i.e. concentration, of analyte in the source;

providing a first test matrix (unit) including a first capture line (region) thereon responsive to the presence of analyte in the sample at a first of the sensitivity levels;

providing a second test matrix (unit) including a first capture line (region) thereon responsive to the presence of analyte in the sample at a second of the sensitivity levels;

providing a first sample from one source;

bringing the first sample into contact with the first test matrix to provide the first capture line thereon an opportunity to indicate the presence of analyte in the sample at at least the first level;

providing a second sample from the same source on an occasion subsequent to providing the first sample; and

bringing the second sample into contact with the second test matrix to provide the first capture line thereon an opportunity to indicate presence of analyte in the sample at at least the second level (see Figure 3; and p4, lines 22-38; p5, lines 1-2; p6, lines 26-34; p13, lines 27-37; p14, lines 6-27; p15, lines 29-32; p23, lines 7-25; p29, lines 35-38; p30, lines 1-21; Example 6 on p48; and "Multiple lane lateral flow test devices" on p52-54).

With respect to Applicant's claims 11 – 13, the first test matrix can include a second capture line responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first test matrix includes providing said second capture region an opportunity to indicate the presence of analyte in the sample

at at least the second level, wherein the second capture line is a measurably distinguishable sensitivity level different than the first of the sensitivity levels, or wherein the first and second sensitivity levels are the same (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; p15, lines 29-32; Example 1 on p39; and Example 6 on p48).

With respect to Applicant's claim 14, the second test matrix includes a second capture line thereon responsive to the presence of the analyte in the source at the first of the sensitivity levels (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; p15, lines 29-32; Example 1 on p39; and Example 6 on p48).

With respect to Applicant's claims 15 and 16, the first and second test matrices can include forming thereon at least three capture lines each responsive to the presence of the analyte in the source at a different of the multiple distinguishable sensitivity levels (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; and p15, lines 29-32).

With respect to Applicant's claim 19, the step of defining the multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the sample is accomplished by forming at least the first capture lines (see Figure 3; and p4, lines 22-38; p5, lines 1-2; and p6, lines 26-30).

With respect to Applicant's claim 20, the method is already discussed above for claim 10, additionally as seen in Figure 3, up to three test units are presented.

With respect to Applicant's claim 21, a substrate 20 is provided to adhere the test units to (see Figure 3).

Claims 10, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kenjyou et al. (US 2004/0096985).

Kenjyou et al. teach a method for monitoring changes in analyte level of a sample source, wherein the method comprises: defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the sample source;

providing a first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels;

providing a second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;

providing a first sample from the sample source;

bringing the first sample into contact with the first unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the first level;

providing a second sample from the source on an occasion subsequent to providing the first sample; and

bringing the second sample into contact with the second unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the second level (see Figure 2; and paragraphs [0015], [0019], [0021], [0027], [0059], [0061], [0070], [0076], [0080], [0123], [0131], [0143]-[0145], [0161], [0165], [0189] and [0193]).

With respect to Applicant's claim 19, the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions (see Figure 2; and paragraphs [0143]-[0145], [0189] and [0193]).

With respect to Applicant's claim 20, , the method is already discussed above for claim 10, additionally as seen in Figure 2, up to five test units are presented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (WO 98/39657) or Kenjyou et al. (US 2004/0096985) in view of Toranto et al. (US 2003/0175992).

The Boehringer et al. and Kenjyou et al. references discussed above both teach methods for monitoring changes in analyte levels in a sample source comprising: providing multiple test devices, each including a plurality of regions, wherein the regions are responsive at a different sensitivity level; bringing a sample from the source into contact with the first of the test devices to determine whether the source contains a level

of analyte sufficient to induce a response thereto in one or more of the test regions; and subsequently bringing a different sample from the source into contact with a second of the test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the second test device. However, both references fail to teach the monitoring is of temporal changes in analyte levels or concentration.

Toranto et al. teach a test system for detection of a variety of analytes in saliva. The test system comprises a single device to test for the presence of a particular analyte of interest. The system also includes storage for a multiplicity of test units that can be accessed and used on one or more occasions, e.g. on one or more separate days, weeks or months. The multiplicity of test units allows for individuals to use more than one assay test on a given occasion, for example, to determine if their analyte concentration has increased or dropped over time. This type of test system wherein the test units can be accessed on separate occasions is important for analytes whose concentrations change over time and need to be monitored, such analytes include alcohol, glucose, ketones, cancer markers (e.g. PSA), illicit compounds, caffeine, hormones, and pathogens (see paragraphs [0055], [0056], [0059], [0126], and [0146]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the methods of Boehringer et al. or Kenjyou et al. the use of the separate test units in monitoring of temporal changes in analyte concentrations as taught by Toranto et al. because Toranto et al. teaches the benefit of including multiple test units in a system in order to allow individuals to use more than

one assay test on a given occasion, for example, to determine if their analyte concentration has increased or dropped over time, which is important for analytes whose concentrations change over time and need to be monitored, such analytes including alcohol, glucose, ketones, cancer markers (e.g. PSA), illicit compounds, caffeine, hormones, and pathogens.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (WO 98/39657) in view of Cole (US 6,656,745).

Boehringer et al. further fail to teach that at least one of the three regions of the first matrix (unit) is responsive to substantially the same level of analyte as one of the three regions in the second matrix (unit), or that each of the regions of the first matrix is responsive to substantially the same level of analyte as one of the regions of the second.

Cole teaches a device and method for multi-level, semi-quantitative immunodiffusion assay. The device utilizes a plurality of binding zones wherein the concentration of binding agent immobilized determines a sensitivity of a given binding zone. Individual binding zones can be reactive for pre-determined levels of analyte in a sample, i.e. each binding zone has a specified concentration of binding reagent. Therefore, the binding zones allow for testing of an analyte over a broad range of concentration. The device normally involves a three-binding zone device or "tri-level test." The number of levels can be tailored in combination with the concentration of binding reagents to alter the sensitivity of the semiquantitative analysis depending on

the particular application or desired precision. The device can detect for the presence or absence of the analyte, i.e. by determining trace levels of the analyte, as well as the semiquantitative amount of analyte present. Thus, the device is beneficial to screen for detection and progress of a particular medical condition, e.g. one threshold level can indicate that the condition is at a preliminary stage, whereas another threshold amount can indicate that the condition is in an advanced state. Such devices are beneficial for testing of analytes that occur in a range, such as prostate specific antigen (PSA) or pregnancy hormone (HCG), whose concentration range determines what, if any medical action is necessary (see column 5, lines 16-67; column 6, lines 7-48; and column 7, lines 16-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include substantially the same sensitivity level in one of the three regions found in both the first and second matrices of Boehringer et al. because Cole teaches the benefit of using a "tri-level test" wherein one of the three regions tests for trace levels of the analyte in order to determine if the analyte is in fact present or absent within the sample. It also would have been obvious to create the regions of the first unit to be responsive to substantially the same level of analyte as only one of the regions of the second in order to allow for testing of an analyte over a broad range of concentration as taught by Cole because Cole teaches the benefit of semiquantitative testing of analytes that occur in a range, such as prostate specific antigen (PSA) or pregnancy hormone (HCG), whose concentration range determines what, if any medical action is necessary.

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Blatt et al. (US 2006/0019404).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jackie DiRamio
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/30/06